



Texas Department of Health

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Commissioner of Health

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Austin, Texas 78756-3189
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Radiation Control
(512) 834-6688

Gary R. Bego
Chief Operating Officer

Charles E. Bell, M.D.
Executive Deputy Commissioner

Re: General License Acknowledgment Self Inspection/Evaluation Form

Dear General License Acknowledgment Holder:

To assist holders of General License Acknowledgments (GLA) in staying in compliance with the GLA requirements the Texas Department of Health (TDH) Bureau of Radiation Control has prepared the General License Acknowledgment Self Inspection/Evaluation with Inventory (Forms CI-40, and CI-40w). There have been numerous occasions when individuals or companies possessing generally licensed devices have lost control of the devices. This usually occurs when the individual or company has failed to properly secure a device from unauthorized removal. Investigations of these incidents usually conclude the cause was related to: the individual who had responsibility for the device terminated employment with the company; the device had been around so long everyone just forgot about it; or the individual having the responsibility for the device was not notified when the device was removed for maintenance, or when the device was moved to another location. The TDH takes the loss of a device seriously and routinely initiates escalated enforcement action against the GLA holder when this occurs. The action includes citing the holder of the GLA for the loss of the device, and a minimum \$8,000 administrative penalty.

These forms were designed to assure (1) all devices are accounted for and have received proper maintenance, (2) there is an individual within the company who is responsible for any devices authorized by the GLA, and (3) the individual is aware of his/her responsibility for the devices.

Enclosures: 1. General License Acknowledgment Self Inspection/Evaluation with Inventory, and
2. Instructions for completion of the forms.

If you need additional forms, or you have questions concerning the completion of the forms, please contact me at 512-834-6688, ext. 2011, or Regional Health Physics Coordinator, Bob Green, ext. 2009.

The General License Acknowledgment Self Inspection/Evaluation, CI-40, and Inventory, CI-40w, should be completed and returned to the Bureau of Radiation Control no later than sixty (60) days following receipt of this correspondence.

Sincerely,

Eric Skotak
Special Inspections and NORM Project
Division of Compliance and Inspection



Texas Department of Health

Bureau of Radiation Control

1100 West 49th Street
Austin, Texas 78756-3189
(512) 834-6688
Fax (512) 834-6654



GENERAL LICENSE ACKNOWLEDGMENT (GLA) SELF-INSPECTION / EVALUATION FORM

Name as listed on GLA: _____ Acknowledgment No. **G0**

Mail Address: _____ City: _____ State: _____ Zip Code: _____

Responsible Person: _____ Tele. No.: _____ Fax No.: _____

Number of Sources: 1. Possessed on date of this report: _____ 2. Possessed at the time of your last report: _____

3. Received since your last report: _____ 4. Disposed/transferred since your last report: _____

Records Location (Physical Address): _____

ADMINISTRATIVE REQUIREMENTS: (Check as Appropriate, and Complete as Applicable)	YES	NO	N/A
1. Do you have the following subsections in Title 25 of the Texas Administrative Code (TAC) available for employee review: §289.201, §289.202(n), (cc), (ff), (gg), & (ww)(1-4), §289.204, §289.205, §289.251, and §289.252(r)? (If "NO," you should request copies of them from the Agency.)			
2a. Are required labels present and legible on all generally-licensed devices containing radioactive sources?			
2b. If "NO" for 2a., were all missing/damaged labels replaced, as required?			
3a. Were all sealed sources in devices tested for leakage, as required (per Agency regulation <u>or</u> the device label)?			
3b. If reportable leakage was confirmed by the test provider, was the Agency notified in writing within 30 days? Report Date: _____ Assigned Incident Number (if known): _____			
4a. Were all device "On-Off" mechanisms tested as required (per Agency regulation <u>or</u> the device label)?			
4b. Employer of individual who conducted tests of "On-Off" mechanisms:			
4c. Were any "On-Off" mechanisms found to be inoperable? Identify (by serial number) any devices having an inoperable mechanism:			
4d. Were all devices listed in 4c. reported to the Agency within 30 days of determining the failure? Report Date: _____ Assigned Incident Number (if known): _____			
5a. Were the tests described in 3a. and 4a., performed by a person specifically licensed to perform the tests OR performed in accordance with the device manufacturer's instructions for that test?			
5b. If the tests described in 3a and/or 4a were performed by your company, are copies of the manufacturer's instructions available for review?			
6a. Have any major services or repairs (e.g., beam alignment, removal of device shielding and/or installation/relocation of a device) been performed on any device since your last self-inspection/evaluation report?			
6b. Name of person(s) who performed any 6a. services: Company Name of each major service provider:			

GLA SELF-INSPECTION / EVALUATION FORM

ADMINISTRATIVE REQUIREMENTS: (Continued)	YES	NO	N/A
7a. Are records documenting all activities described in 3, 4, and 6 maintained for inspection, as required?			
7b. Is all information required by §289.251(k)(1)(E)(iv) present on these records?			
8a. Has any failure of, or damage to, the radioactive material source shielding been identified? If "YES," specify the device(s) by serial number:			
8b. If "YES" for 8a., was use of that device suspended immediately?			
8c. If "YES" for 8a., was it reported to the Agency within 30 days? Report Date(s): _____ Assigned Incident Number(s): _____			
8d. Was any device listed in 8a either: 1) repaired by the manufacturer or by another Specific Licensee authorized to repair the device(s); or, 2) "disposed" by transfer of the device to a specific licensee authorized to possess the radioactive material? Please specify which method was used for each device:			
9. Identify any devices (by serial number) which were permanently transferred/disposed since your last self-inspection/evaluation:			
10a. Were any generally-licensed devices transferred to another general licensee (i.e., site purchased)? [This can be done ONLY in accordance with §289.251(k)(1)(E)(xi).]			
10b. If "YES," for 10a., was a report of the transfer submitted to the Agency within 30 days?			
10c. Did the report contain all information required by §289.251(k)(1)(E)(x) and (xi)(I)?			
11a. Were any devices/sources lost since the last evaluation? If "YES," list the serial number(s) below:			
11b. Were all devices listed in 11a. reported to the Agency, as required? Report Date(s): _____ Assigned Incident Number(s): _____			
12a. Do you have any generally-licensed devices/sources not in use, inoperable, or in storage at this time?			
12b. If "YES" to 12a., are all such devices secured against unauthorized removal or disposal?			

Questions 14 & 15 are to be answered only if portable/mobile devices are possessed under your GLA	YES	NO	N/A
13. Number of portable/mobile generally-licensed devices currently possessed:			
14a. Are assignment (utilization) logs maintained for each portable/mobile device possessed?			
14b. Is all information required by §289.251(k)(1)(E)(v) present on the log(s)?			
15a. Are copies of appropriate operating and instruction manuals available at each temporary job site?			
15b. If a portable/mobile device is being utilized at a temporary job site, is the assignment (utilization) log for that device maintained for inspection by the Agency at that job site, as required?			

Cross-reference for Title 25 Texas Administrative Code (TAC) Chapter 289:

§289.201 [formerly Part 11]; §289.202 [formerly Part 21]; §289.204 [formerly Part 12]; §289.251 [formerly Part 40]; §289.252 [formerly Part 41]

Signature _____ Date _____

GLA SELF-INSPECTION INVENTORY< < *SUBMIT THIS INVENTORY TO THE AGENCY and please maintain a copy for inspection by the Texas Department of Health* = = =

DEVICE SERIAL NUMBER L								
Device Manufacturer (Name of Company):								
Device Model Number:								
Isotope (ex. Cs-137, Co-60, Fe-55, Cd-109, Ir-192):								
Activity of source in millicuries (mCi) or Curies (Ci):								
Sealed Source Serial Number:								
Physical Location of the device within your facility:								
Date the device was received at your facility:								
Device Label present and legible? ("Yes" / "No")								
Leak Test Dates (since last report):								
"On-Off" Mechanism Test Dates (since last report):								
Date the device was transferred, or sent for disposal:								

DEVICE SERIAL NUMBER L								
Device Manufacturer (Name of Company):								
Device Model Number:								
Isotope (ex. Cs-137, Co-60, Fe-55, Cd-109, Ir-192):								
Activity of source in millicuries (mCi) or Curies (Ci)								
Sealed Source Serial Number:								
Physical Location of the device within your facility:								
Date the device was received at your facility:								
Device Label present and legible? ("Yes" / "No")								
Leak Test Dates (since last report):								
"On-Off" Mechanism Test Dates (since last report):								
Date the device was transferred, or sent for disposal:								

Details of any major repairs performed on any device: _____.

Inventory prepared by: _____ Date prepared: _____.

Instructions for the GLA Self Inspection/Evaluation Form -- (Form CI-40 and CI-40w)

The GLA Self Inspection/Evaluation and Inventory are to be completed and returned within 60 days of receipt to:

Texas Department of Health
Bureau of Radiation Control
Division of Compliance and Inspection
Attn: Mr. Eric Skotak
1100 West 49th Street
Austin, Texas 78756-3189

The attached form specifies that “Yes” or “No” blocks be checked in response to some questions, and that blanks be completed with specific information in response to others. (Also, in some cases, “N/A” is the appropriate blank to check.) If you do not have sufficient room to respond to any question, you may include one or more supplemental pages with your submission. On each additional page, please include your General License Acknowledgment Number, and also reference the block number to which each response applies. *If you have questions concerning the completion of these forms, please contact either of the following at (512) 834-6688: Eric Skotak, at ext. 2011, or Bob Green at ext. 2009.*

Maintain a Copy of the Completed Forms for Your Records.

Instructions for Completing Page 1 of Form CI-40

Company Name..... The GLA Holder. This is “Item 1” of your GLA.

Acknowledgment No.... This is “Item 4” of your GLA.

Address, City, Zip..... This is “Item 3” of your GLA.

Contact Person..... This is “Item 2” of your GLA. This person is also referenced in a numbered “Condition” on your GLA.

Phone and Fax Nos..... These are the telephone and fax numbers for the “Contact Person” listed on your GLA.

Note: 25 TAC '289.251(o)(1) and a Condition on your GLA require you to notify this Agency, in writing, within 30 days of any change which renders information in the GLA no longer accurate. Please direct any such notification, when necessary, to Mr. Phil Shaver, Division of Licensing, Registration, and Standards. Your correspondence to Mr. Shaver should also include a specific request to amend your GLA accordingly. **To expedite processing, amendment requests may be faxed to (512) 834-6690.**

Administrative Requirements:

Block #: Explanation

- 1 Self-explanatory.
- 2a Proper and legible warning/information labels are required on all devices possessed under your GLA.
- 2b If any labels were found to be missing or illegible, they must be replaced with new manufacturer-supplied labels.
- 3a The sealed source(s) of radioactive material installed in any device possessed under your GLA must be tested for leakage/contamination at six-month intervals...or at such other intervals as may be specified on the device label.
- 3b Sources found to have 0.005 Ci or more of leakage/contamination must be reported to the Agency within 30 days of determining the leakage. Provide the REPORT DATE and the assigned INCIDENT NO. (if known) for any leaking sources reported.
- 4a “On-Off” mechanisms for all devices possessed under your GLA must be periodically tested for proper operation.
- 4b Self-explanatory.
- 4c If any “On-Off” mechanisms were found to be inoperable, list the serial number of any affected device.
- 4d Any inoperable mechanism must be reported to the Agency within 30 days of determining the failure. Provide the REPORT DATE and the assigned INCIDENT NO. (if known) for each device having an inoperable “On-Off” mechanism.
- 5a Required testing (for leakage/contamination and proper operation of the “On-Off” mechanism) can be performed either by the GLA Holder or by a specifically licensed person. The tests must be conducted in accordance with instructions provided by the manufacturer of the device, unless performed by an entity specifically licensed to provide the service.
- 5b The General Licensee is required to maintain (for review by the Agency) copies of all manufacturer instructions if the tests are performed by the General Licensee.
- 6a Sometimes, one or more component failures require the repair or replacement of a generally-licensed device. Major servicing of these devices may not be performed by the General Licensee...UNLESS specifically authorized to do so by a Condition on the GLA.
- 6b Write the name of any individual technician(s) who performed major ONSITE servicing, repairs and/or relocation of your devices. Also, name any company whose personnel performed major device servicing/repairs...either onsite or at their own facility.

Instructions for Completing Page 2 of Form CI-40

Block # Explanation

- 7a Records of leak testing, mechanism testing, and major servicing must be maintained for inspection by the Agency.
- 7b For records described in 7a. to be complete, they must include all information specified in the referenced regulation.
- 8a If there has been any failure or damage or indication of a possible failure or damage to shielding of a device authorized by the GLA, identify the devices by serial number. Please note that actual damage does not have to occur; there only has to be a significant indication of possible failure or damage to the shielding.
- 8b & c If the response to Block 8a. is "Yes," any such devices must be removed from service and reported to the Agency.
- 8d Self-explanatory.
- 9 Self-explanatory.
- 10a Possession and control of generally-licensed sources may not be transferred to another general licensee except under very limited circumstances. (Usually the device must be returned to the manufacturer FIRST, and then redistributed to the new general licensee.)
- 10b & c If generally-licensed radioactive material is transferred to an entity which is not specifically licensed to receive it, this Agency must be notified, in writing, of certain information within 30 days.
- 11a & b "Loss-of-control" (loss or theft) of a generally-licensed source constitutes an INCIDENT; and, specific information must be reported to this Agency immediately, and also in writing within 30 days of the event.
- 12a Devices in this category could include any which have been removed from their place of installation or any which may have been purchased and delivered, but not installed.
- 12b Generally-licensed radioactive material must be physically secured against unauthorized removal from the storage/use location.

For Portable or Mobile Devices:

- 13 Self-explanatory. (Insert "0" if no such devices are possessed.)
- 14a Assignment/Utilization Logs (check-out/check-in records) must be maintained for each portable/mobile device possessed under your GLA.
- 14b Information specified in the referenced regulation must be included on all assignment/utilization records.
- 15a Copies of appropriate operating and instruction manuals (from device manufacturer), plus any additional procedures established by the General Licensee, must be available for each portable/mobile device authorized by your GLA.
- 15b During the time that a portable/mobile device authorized by your GLA is in use at a temporary jobsite (any site not specifically listed on your GLA), the daily assignment/utilization log must be available for inspection by this Agency at the jobsite.

SIGN and DATE at the Bottom of Page 2.

Instructions for Completing Form CI-40w – Physical Inventory (The form is self-explanatory. It is to be completed, signed, dated, and submitted to the Agency.)

To avoid inadvertent violations of the regulations, the following notification requirements should be reviewed periodically by the "Contact Person:"

- 25 TAC '289.251(o)(1).....Whenever changes result in inaccurate information being present on your GLA (Company Name, Mailing Address, Physical Address, or the "Contact Person," etc.
- 25 TAC '289.251(k)(1)(E)(viii).....Whenever any of the following is determined: radioactive source leakage/contamination >0.005 Ci; OR, failure, real or potential damage/failure involving any Aon-off@ mechanism or source shielding.
- 25 TAC '289.251(k)(1)(E)(x).....Whenever a device is permanently transferred to a Specific Licensee (not for repair and return).
- 25 TAC '289.251(k)(1)(E)(xi)(I)....Whenever a device is transferred to a General Licensee in accordance with this clause.
- 25 TAC '289.202(xx)(1) or (2).....Whenever circumstances have required immediate or 24-hour notification. (See Below)

In addition to the preceding, a General Licensee must also notify this Agency: in writing, no less than 30 days prior to vacating a storage/use location designated on the GLA [25 TAC '289.251(n)(2)]; immediately in writing when the decision is made to terminate activities involving all generally-licensed devices and to transfer all such devices [25 TAC '289.251(n)(1)]; in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy [25 TAC '289.251(m)(3)]; immediately if an event described in 25 TAC '289.202(ww)(1)(A) occurs (i.e., the loss or theft of a source-containing device); within 30 days if an event described in 25 TAC '289.202(ww)(1)(B) occurs (i.e., the loss or theft of a source-containing device); immediately if an event described in 25 TAC '289.202(xx)(1) occurs (i.e., an INCIDENT), and within 24-hours if an event described in 25 TAC '289.202(xx)(2) occurs (i.e., an INCIDENT).